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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 10/741,790      | 12/19/2003  | Christopher C. Fraser | MPI00-535OMNICN1M   | 6648             |

30405 7590 11/01/2006

MILLENNIUM PHARMACEUTICALS, INC.  
40 Landsdowne Street  
CAMBRIDGE, MA 02139

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| EXAMINER |
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JIANG, DONG

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1646

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/741,790

Applicant(s)

FRASER ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 86-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 86-103 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's third preliminary amendment filed on 11 August 2006 is acknowledged and entered. Following the amendment, the original claims 1-5, 8-14, 16 and 19-25 are canceled, and the new claims 86-103 are added.

Currently, claims 86-103 are pending.

Upon reviewing the new claims, second restriction requirement is warranted.

#### **Election/Restrictions**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 86-92 and 95-101, drawn to an antibody specific to said polypeptides, and a method of making thereof, classified in class 530, subclass 387.9.
  - II. Claims 93, 94 in part, 102, and 103 in part, drawn to an antibody conjugated to a therapeutic moiety, wherein the therapeutic moiety is a cytotoxin, classified in class 424, subclass 183.1
  - III. Claims 93, 94 in part, 102, and 103 in part, drawn to an antibody conjugated to a therapeutic moiety, wherein the therapeutic moiety is a therapeutic agent, classification depending upon the chemical entity of the therapeutic agent.
  - IV. Claims 93, 94 in part, 102, and 103 in part, drawn to an antibody conjugated to a therapeutic moiety, wherein the therapeutic moiety is a radioactive, classified in class 424, subclass 181.1

The inventions are distinct, each from the other because:

Invention I is distinct from Inventions II-IV because the products of Inventions II-IV comprise an additional active ingredient besides the antibody itself, i.e., a therapeutic moiety, which is a distinct chemical entity from the antibody, and thus, separate searches are required.

Inventions II-IV are distinct, each from each other because each therapeutic moiety is a distinct chemical entity with respect to both structure and function, and thus each requires separate search.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, regardless of which Invention applicants elect above, further **restriction** is required under 35 U.S.C. 121:

A. Elect *one* specific polypeptide from the following: SEQ ID NO:417 and 419.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs represents a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of the invention from Groups I-IV, and an election of the invention from Group A, to be examined even though the requirement be traversed (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention. Applicant is advised that neither I-IV nor A is species election requirement; rather, each of I-IV and A is a restriction requirement.**

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Species election**

This application contains claims directed to the following patentably distinct species: claims 92 and 101 recite six detectable labels, and they are: enzymes; prosthetic groups; fluorescent materials; luminescent materials; bioluminescent materials; and radioactive materials. The species are independent or distinct because they are distinct chemical entities, and each requires a separate search of the prior art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 91 and 100 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

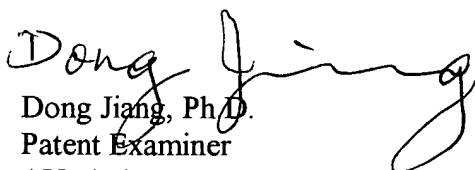
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**Advisory Information**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Dong Jiang, Ph.D.  
Patent Examiner

AU1646  
10/24/06